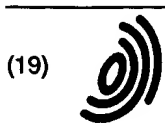


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(54) Multiple fire endoscopic stapling mechanism

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(56) References cited:

EP-A- 0 094 752	EP-A- 0 154 815
EP-A- 0 180 820	WO-A-82/01308
WO-A-89/10094	GB-A- 2 014 503
US-A- 3 815 476	US-A- 4 043 504
US-A- 4 403 693	

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Description**FIELD OF THE INVENTION**

[0001] Generally, this invention relates to repair mechanisms to be used endoscopically. More specifically, this invention relates to repair mechanisms which allow for the repair of hernias. Most specifically, this invention relates to a hernia repair mechanism which describes a unique stapling mechanism for endoscopically fastening a prosthetic patch over a hernia, as well as a unique loading and alignment system for use with this repair mechanism, as well as the application of metallic staples for the endoscopic approximation of herniated tissue.

BACKGROUND OF THE INVENTION

[0002] With the proliferation of endoscopic surgery, it has been realized that there are many procedures typically performed in open surgery which are now capable of being performed endoscopically. A trocar, which is a pointed piercing device, is sent into the body with a cannula placed around the trocar. After the trocar accomplishes piercing of the abdominal walls, it is removed and the cannula remains in the body. Through this cannula, endoscopic procedures are possible. Generally, these endoscopic procedures take place under insufflation. Some of the more typical procedures have been gall bladder removal, tissue repair and sterilization procedures such as occluding of the Fallopian tubes.

[0003] Surgeons realize that it may be possible to perform additional procedures endoscopically, once the proper materials and mechanisms become available for performing these procedures. One of the more basic, and quite logical extensions of current endoscopic procedures has been focused on repair of hernias. It is realized that to have the capability of performing hernia repair endoscopically will serve the medical community in many ways. Specifically, it is realized that endoscopic hernia repair will allow the patient to recuperate more rapidly, and without the more than likely extensive physical therapy currently practiced as a result of such "simple" procedures.

[0004] Moreover, it is realized that hernia repair procedures may contain aspects which are applicable in other procedures. For instance, if it is possible to cover, or reinforce and constrain a hernia it may be possible to apply this procedure to other vessels or organs, in much the similar manner. Also, it is realized that once a device becomes available wherein hernias can be repaired, many of these functional components on these devices would be useful in other devices capable of performing other procedures. Also, naturally, these mechanisms may be useful on procedures wherein open surgery is performed.

[0005] Document EP-A-0 180 820 discloses a cartridge of staples in which a plurality of staples are held.

Each of the staples has a crown and a pair of legs. The distal ends of the legs contact the crown of the preceding staple in the cartridge. The crown of each staple may have notches for aligning the distal ends of the legs. US-A-4 196 836 incorporated in EP-A-0 180 820 discloses a stapling mechanism with staples according to the preamble of Claim 1.

SUMMARY OF THE INVENTION

[0006] According to the present invention there is provided, in combination, a staple and a stapling mechanism as defined in the claims.

[0007] Therefore, it is an object of the invention to provide a hernia repair device.

[0008] It is yet another object of the invention to provide a device for the permanent approximation of tissue using metal fasteners, and, specifically a hernia repair device where hernia repair can be accomplished endoscopically.

[0009] It is yet another object of the invention to provide a hernia repair device wherein mesh or prosthetic device can be applied about the hernia so that the hernia is permanently covered, in order to constrain internal organs such as the intestines.

[0010] It is yet another object of the device of the invention to provide a device which is capable of sealing or approximating tissues in much the same way as mesh is applied over the hernia.

[0011] Another object of the invention is to provide a hernia repair device which is capable of applying staples to tissues with improved staple alignment mechanisms, as well as with improved loading and ejecting mechanisms. In addition, it is perceived that such a mechanism may be capable of a multiple-load feature.

[0012] An additional object of this invention is to provide a unique staple configuration for use with a hernia repair mechanism.

[0013] A final object of the invention is to provide a reliable feed mechanism to a multiple load surgical stapler.

[0014] As a result of this invention, a hernia repair device is disclosed where the device is capable of attaching a prosthetic over the herniated tissue. The device holds and forms a staple in place so that the herniated tissue is secured and clamped. The mechanism accomplishes this procedure endoscopically, through a trocar tube. Of course, the mechanism is capable of applying the staple directly to tissue without a prosthetic wrap. The stapler is currently perceived as a single fire device, but may be converted quite readily into a multiple load mechanism.

[0015] Importantly, the stapler has a unique loading, forming and ejecting mechanism. Three parts of the mechanism are designed to slide one upon the other in order to provide the sequence of operations necessary to place the staple. The anvil portion of the stapler is the stationary reference, upon which a staple former slides upon the anvil; a staple holder slides upon the former.

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The staple holder is spring biased against the staple former, so that a biasing force is exerted by the holder against the anvil portion of the instrument. The spring which biases the former to the holder is also a trigger return, eliminating the need for an external spring on the device. With this biasing force, a staple may be securely loaded from either a cartridge or a magazine into the instrument. The staple holder holds the staple by use of this biasing force against the stapler anvil.

[0016] As the instrument is fired, the staple former exerts a forming motion against the staple such that it is clamped about either tissue or mesh. As the staple is formed, the staple former comes into direct contact with a camming surface on the staple holder. This camming force causes the staple holder to eject the staple from the anvil after it has been formed. Ejection is accomplished without any twisting motion of the surgeon's wrist, as is currently accomplished with some staplers. Release of the instrument trigger causes the staple holder and former mechanisms to return to their initial positions.

[0017] Uniquely, this mechanism also discloses a staple shape which allows for more secure alignment of this staple on the stapling surface. The staple is described with a notched shape in its crown. This notched shape mates with a similar notched shape formed on the staple holder so that the staple is automatically held and centered against the anvil. In this way, the staple is always secured, such that it is capable of being centered and applied uniformly each time the hernia repair mechanism is operated.

[0018] Furthermore, a stapler is disclosed which additionally contains an enhanced staple containing a pair of external notches. These notches provide a loading platform upon which the subsequent staples may be placed.

[0019] Finally, in the case of the multiple load mechanism, an improved lifter configuration is provided. This lifter mechanism contains a positive stopping surface in the portion of the staple cartridge upon which the staple lifter mechanism slides. This improvement creates reliable feeding and staple positioning.

[0020] These and other objects and descriptions and disclosures of the present invention will be more readily understood from the attached Detailed Description of the Drawings taken in connection with the Detailed Description of the Invention.

DETAILED DESCRIPTION OF THE DRAWINGS

[0021]

Figures 1 and 1A are perspective final and assembly drawings respectively of a stapling mechanism;

Figure 2 is a side elevation view;

Figures 3 and 3A are plan and elevation views of

the fully retracted stapling mechanism;

Figures 4 and 4A are plan and elevation views of the stapling mechanism as the staple has begun to be formed;

Figures 5 and 5A are elevation and plan views of the staple as it is formed on the anvil;

Figures 6 and 6A are final positions of the staple as it is being ejected from the stapling mechanism;

Figures 7A, 7B and 7C are plan views of the loading procedure of a single shot mechanism of this mechanism;

Figures 1-7 are not encompassed by the present invention.

Figures 8A, 8B and 8C are plan-views of possible stapler configurations of this invention, including a novel alignment feature for the staples;

Figure 9 is a plan view of a cartridge of staples useful for multiple firing mechanism using this invention;

Figure 10 is a cross-sectional view of the multiple fire mechanism of Figure 9;

Figure 11 is a detailed cross-sectional view of the cartridge loading mechanism of this invention;

Figure 11A is a cross-sectional view of the cartridge taken across lines 11A-11A of Figure 11;

Figure 12 is a cross-sectional view of the staple loading track as seen across line 12-12 of Figure 11;

Figure 13 is a plan view of a new configuration staple held in the staple stack used in this mechanism;

Figure 14 is a perspective view of a single staple as seen in Figure 13;

Figure 15 is an cross-sectional view of the staple stack of Figure 11, as taken across lines 15-15;

Figure 16 is a perspective view of the improved staple lifter of this invention; and

Figure 17 is an underside view of an embodiment of the stapler cartridge of this invention.

DETAILED DESCRIPTION OF THE INVENTION

[0022] There is described in Figures 1, 1A and 2 an endoscopic hernia repair stapling mechanism 10 useful

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to apply mesh and prosthetics to herniated tissues or organs. This endoscopic mechanism is placed through a trocar cannula or tube, typically an Endopath™ Trocar manufactured by Ethicon, Inc., Somerville, New Jersey 08876. The endoscopic portion 12 of the hernia repair mechanism 10 fits snugly within a cannula of a trocar, so that the procedure can take place within the cannula and in the abdominal cavity.

[0023] It is intended to use this device so that the stapler will apply a mesh around the herniated organ and then apply a staple either into the tissue or into the prosthetic mesh itself. Therefore, the stapling mechanism 10 must have some unique features. Preferentially, it is desirable to have a stapler which after the staples are formed does not need to be twisted to release the staples from the mechanism. This is true for a number of reasons. First, it is desirable to have a staple which comes off of the mechanism smoothly. Second, it is also desirable to have staple which will not tear tissue or inadvertently reposition the prosthetic which is applied over the herniated tissue, both while the staple is being applied and in removal, because the staple has been clinging to the stapler. Third, this feature of itself makes this type of stapler more reliable by more readily guaranteeing proper positioning and application of the staple by the user.

[0024] As seen in Figures 1 and 1A, there is described a trigger which is useful for firing the stapler. The trigger is connected to a driving mechanism which is capable of driving both the staple former and staple holder at the opposite end of the stapler. Also, this trigger mechanism is capable of advancing staples incrementally when they are loaded in a magazine type cartridge as is typically found in staplers of this sort. Finally, this trigger mechanism is capable of being used with a rotatable endoscopic portion, regardless of orientation of the stapling mechanism. A typical drive and rotatable mechanism can be found in EP-A-442482.

[0025] The trigger 14 and driving mechanism 16 of this invention actuate stapler, mechanism 18 along the endoscopic portion 12 of the stapler. This driving mechanism 16 is capable of firing a staple 20 as is seen in Figures 3 through 6, and 3A through 6A. It is to be understood that, as is seen in Figures 1 and 2, that this driving mechanism 16 may be separated from the portion of the mechanism 10 containing trigger 14. This allows interchanging of sizes of staples 20, and cleaning of the driving portion 16 of the mechanism 10, if this is not a reusable device. Typically, attachment may occur at or near the screw portion 22 which allows rotation along the endoscopic portion of the mechanism.

[0026] Importantly, as seen in Figure 1A, this device has a sheath 15, which is slightly larger in diameter than the stapler shaft 17. This sheath 15 is placed over the proximal end of the stapling mechanism during insertion into a trocar cannula and into the body cavity. Thereafter, a sliding mechanism (not shown) operates to slide sheath 15 distally over shaft 17.

[0027] As is seen in Figures 3 through 6 and Figures 3A through 6A, there is described in the drawings a method for both holding and firing staples 20. As is seen in Figure 3 and 3A, the holder 24 is spring biased against the former 26. Both the former 26 and the holder 24 are slidable in relationship to the stationary anvil 28. The stationary anvil 28 has at its end an anvil portion 30 around which the staple 20 may be formed. The staple holder 24 has a ledge 32 on which the crown 34 of the staple 20 may be seated. The staple holder 24, because it is biased by the former 26 in a position distal to the instrument, is able to maintain the staple 20 held against the anvil portion 20 at all times, until it is desired to eject the staple 20. This ejection occurs after the staple 20 has been formed.

[0028] Thus, as seen in these figures the staple 20 is initially positioned so that it is ready to engage either tissue or mesh wrapped around a herniated organ. The holder 24 securely maintains the crown 34 of staple 20 against the anvil portion 30, and the former 26 is retracted so that vision by the user of the staple 20 is not obscured when it is initially placed. (Of course, since this procedure is done through an endoscopic device, the viewing of the procedure must be done through a fiberoptic mechanism emplaced into the abdominal cavity through the cannula of a separate trocar device).

[0029] As is seen in Figures 4 and 4A, the holder 24 still maintains the staple crown 34 against the anvil portion 30, and now by squeezing the trigger 14 on the forming end 13 of the mechanism 10, the former 26 has begun to form the staple 20. The former legs 36 contacts the staple 20 at the end of the crown 34. These legs 36 of the former 26 entirely form the staple 20 about the anvil portion 30. As can be seen in Figure 4A, the camming portion 38 of the former 26 placed underneath the staple holder 24 has moved nearer to the camming portion 40 of the staple holder 24. In this way, the device is sequentially readying the staple 20 for ejection after forming.

[0030] As can be seen in Figures 5 and 5A, the staple 20 has now been entirely formed by the former 26. The former 26 is at its maximum position distally of the trigger 14. The staple 20 is entirely formed in a box shape and, if it has been secured on a prosthetic mesh covering a segment of herniated tissue, has entirely pierced and gripped the mesh. Of course, it is to be realized that the staple 20 can be placed into tissue so that the prosthetic mesh is permanently attached to be placed within the tissue.

[0031] As can be further seen in Figures 5 and 5A, the camming portion 38 of the former 26 has contacted the camming portion 40 of the staple holder 24. The former 26 has continued to be biased against the staple holder 24, so that the staple holder 24 holds the staple 20 against the anvil portion 30. Spring 42 which causes the biasing force is now fully compressed. With full compression, the staple holder 24 is now readying itself for ejecting the staple 20.

[0032] As can be seen in Figures 6 and 6A, the staple former 26 has now progressed so that the camming means 38 on the staple former 26 have fully contacted and cammed the camming means 40 on the staple holder 24. The staple holder 24 has been caused to be displaced laterally from the anvil 28. With such lateral displacement, the ledge 32 holding the staple against the anvil portion 30 has now moved to a position away from the anvil portion 30. In so doing, the staple 20 is now free-standing from the anvil 28. Thus, with retraction of the device from the forming site, the staple is free floating. Because the staple has been fully formed in both mesh and tissue, the staple 20 is properly placed and there is no further need for maintenance of the staple on the mechanism.

[0033] This unique staple forming sequence accomplishes full holding of staple 20 and full ejection without twisting or further emplacement of the staple 20, except that placement performed by the mechanism. This allows unique advantages to the user. For instance, the user is able to fully discern point of placement. He then retracts the stapler 10 after forming the staple knowing placement has been accomplished. This improvement allows the user also to focus on the point of placement with a fiber optic viewing mechanism and not worry about losing focus of the stapling site. Also, the user is now able to retract the mechanism 10 without worry of what adverse effects caused by twisting the mechanism away from the staple 20. These features all represent improvements over present devices.

[0034] As can be seen from Figure 9, there is disclosed a staple cartridge 50 much like the cartridge described in the previously referenced EP-A-442482.

[0035] This cartridge 50 holds a number of staples 20. It sequentially advances the staples 50 by a spring mechanism. The staples 20 are moved into position, so that this alternate embodiment stapler may be considered a multiple fire device. As the trigger 14 is retracting so that the staple holder 24 and former 26 are returning to their original positions within the mechanism, the cartridge 50 as described in Figure 9 is providing an additional staple 20 to the stapling site. A staple pick-off mechanism may appropriately take the lead staple 20 in cartridge 50 and place it over staple former 26 and holder 24. A separate internal mechanism will need to activate holder 24 to create room for staple 20 between holder 24 and anvil portion 30. Then, staple 20 is placed on ledge 32, and all the loading mechanisms retract. Of course, because the staple holder 24 has appropriately been placed to hold the staple 20 in position, it is quite easy to begin a new firing function. Also, the next staple 20 in the cartridge 50 is ready for loading after the next firing sequence.

[0036] As seen in Figures 2, 7A, 7B and 7C, in the described "single-shot" mechanism the staple 20 may be contained in an external cartridge 44 of staples. Generally these staples may number roughly 20 to the cartridge 44. A staple 20 is capable of being placed

within the holder 24 as is seen in the Figures. As seen in Figure 7A, the anvil 28 and holder 24 are advanced toward the staple 20 held within the cartridge 44. As seen in Figure 7B, the anvil 28 has been fully placed into the cartridge so that the wedge shaped underside 46 of the anvil 28 matches wedge shaped portion 48 of the cartridge 14. Now, the spring biasing force exerted by the former 26 against the holder 24 has been overcome so that the holder 24 is pushed proximally to the trigger 44. When this occurs, room is made between the anvil 28 and ledge 32 of the holder 24 so that the crown 30 of the staple 20 may be placed on the holder ledge 32. As can be better seen in Figure 7C, the crown 34 is wedged between the holder 24 and the anvil portion 30. Thus, the crown 34 of the staple 20 is seated on the holder ledge 32, and is securely held tightly by the biased holder 24 and the anvil 28. The mechanism 10 is removed from the cartridge 44 so that the staple 20 is removed from its moorings in the cartridge 44. The anvil portion 30 forces the staple crown 34 and ultimately the staple legs 33 out of the cartridge 44, and the staple 20 is held securely within the stapling device 10.

[0037] Of course, it is to be realized that any of these mechanisms securely hold and fire such staples. However, it is further desirable to have a proper alignment mechanism to hold the staples in place. Some such alignment mechanisms are described in Figures 8A, 8B, and 8C. As is seen in Figure 8A, a staple 120 is placed between holder 124 and anvil 130. The preformed hexagonally shaped staples 120 are formed so that the legs 122 formed around the crown 134 self-center the whole staple 120 on anvil 130.

[0038] Alternately, as in Figure 8B, a staple 230 may be formed with serrations 222 on one of the sides of crown 234. The serrations 222 mesh with serrations 226 on holder 224. Alternately, anvil 250 may have serrations 234, so that there is even more secure placement and centering of staple 220 holder, and against the anvil 234.

[0039] Finally, as seen in Figure 8C, there is created a notch 336 to the staple crown 334. This notch 336 fits against the anvil 330 at a notch 338 made in anvil 330. Furthermore, a notch 328 is made in holder 326. These notches 328, 336, 338 maintain triple alignment of the staple 320 held within the holder 324 and anvil 330. The user is assured that staple 320 will form with equal size legs 340 on either side of the stapler former. A box formed staple shape is assured.

[0040] In use the mechanism 10 of this invention is created so that it grasps a staple 20 between the staple holder 24 and anvil 28. This can either be done from a external cartridge 44 of staples 20 or a magazine 50 of staples within the mechanism 10. Of course, the endoscopic portion 12 of the stapler has been attached to the driving mechanism 16 and trigger 14. The endoscopic portion 12 may be rotatable if so desired. Once a proper place has been derived for staple 20 emplacement, the endoscopic portion 12 is locked in place so that place-

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ment can be assured.

[0041] Trigger 14 is fired and the unique holding and ejecting mechanism allows the staple 20 to be held, formed and ejected in a repeatable and assurable manner. Also, once the staple 20 has been formed, ejection is accomplished without twisting or any other function, other than retraction of the repair device 10 from the staple site. Because the staple 20 is formed in a box shape, it is found useful to apply to tissue and mesh prosthetics held around the tissue, or mesh prosthetics covering herniated tissue. In this fashion, the mechanism 10 applying staple 20 is able to hold the mesh in place permanently, or until healing occurs.

[0042] As seen in Figures 10-16, there is described a further embodiment of a multiple fire mechanism compatible with the cartridge 50 described in Figure 9 and above. The configuration of this stapling mechanism 150 obviates the need for a staple holder as in the single-fire device. Rather, a staple feeder and driver combination control the position of the staples throughout the firing, as will be explained further herein. The handle 200 containing an actuator mechanism 220 operates identically to those described in EP-A-442482. This actuator mechanism operates to cause a drive 210 to operate within the cartridge portion 240 of the mechanism. As in EP-A-442482, the cartridge 240 is able to rotate about actuator 220 and handle 200 of this stapling mechanism 150. Also, driver 210 is able to be oriented in any position for firing. Naturally, it is cartridge 240 which is circular in shape and capable of fitting in the cannula of a surgical trocar, like the 10-11mm Endopath™ Trocar marketed by Ethicon, Inc., Somerville, New Jersey 08876.

[0043] As seen in Figures 11, 13, 14 and 15, there are a plurality of staples 230 located in cartridge 240. Staple 230 contains a pair of legs 232 separated by a proximal portion or crown 234. These staples 230 are generally at least twelve in number, lie flat along the longitudinal axis of cartridge 240, and are positively urged toward the distal end of cartridge 240 near the anvil 250. Cartridge 240 may ideally be rotatable about handle 200.

[0044] This new endoscopic staple 230 has been developed with a notch 236 in each of the sides adjacent legs 232 in the proximal portion 234 of the staple 230. With this design, the points 232a, 232b of the following or next sequential staple 230 rest in the notches 236 of the preceding staple 230, and each of these staples 230 can be constrained to match the motions of the lead staple. With a number of notched staples 230 lined in a stack and constrained by staple track 252, the stack acts as a single long member which is difficult to rotate. The staples 230 therefore feed in line without rotating in track 252 and are consequently, less likely to jam.

[0045] As seen in Figures 11, 11A, 12, 15 and 16, this stapling mechanism 150 contains a firing system similar to that of EP-A-442482, and that of the single fire mechanism 10 described above. There is contained in cartridge 240, a driver 210 which causes staples 230 to be

formed. Feeder 260 enables a first staple 230 to be placed in position for firing. Lifter 270 takes the forwardmost of staples 230 from stack 252 to be placed in the path of driver 210, in order to be formed. Ejector 280 kicks formed staples from the mechanism 150.

[0046] Firing staples 230 from the stapling mechanism 150 occurs as described below, starting with a staple formation stroke just completed. With the trigger 220 fully engaged, the drive 210 rests against the formed staple 230, which in turn rests against the anvil 250. In this state the staple 230 is ready to be kicked off by ejector 280 which acts as a leaf spring. Lifter 270 is in its fully forward position, having operated to place the forwardmost staple 230 in the path of driver 210 to be formed at anvil 250. With the lifter 270 positioned in this manner, a staple 230 has been fed by the feeder 260 behind the stack of horizontally loaded staples 230 (Figure 13). Since the staple track 252 in the cartridge 240 supports the staple 230 on its way to the lifter 270, a rearward staple 230 cannot rotate or ride over a staple 230 in front of it. Once positioned beneath lifter 270 the staple 230 is not held within track 252 any longer, but is supported between staple plate 290, the stops 300 and the lifter 270 underside.

[0047] As the firing process continues, the driver 210 is retracted by releasing the trigger 220 of the handle 200; the ejector spring 280 kicks off the previously formed staple 230 since the staple is no longer held fast against the anvil 250 by the driver 210. At the same time the lifter 270, forced by a spring 274 which acts as a coil spring, but restrained by the surface of driver 210, starts to drop the next staple 230 to be formed into place in front of the driver 210. Meanwhile, the feeder 260 is forcing the stack of staples toward the lifter 270, with the lead staple 230 restrained from double feeding by the rear surface 271 of the lifter 270 which, provides a stopping surface for the inside of the staple crown 234. Once the driver 210 is pulled back fully by releasing the trigger, the staple 230 is positioned (by the now fully depressed lifter 270) in front of the driver 210 for firing. As the trigger 220 is pulled, the driver 210 moves forward, forces the lifter 270 and staple plate 290 out of its way while engaging the staple 230, along legs 232, and, as well, crown 234 on formation of the staple 230. Moving the staple 230 forward leads to final formation around the anvil 250. During these final stages of staple fire, the lifter 270 and staple plate 290 are simultaneously forced aside by the driver 210 such that the feeder 260 can force the staple stack 252 forward to put in place the next staple for firing, positioned below the lifter 270.

[0048] As can be seen in Figures 15, 16 and 17, rather than rely on the lifter surface features 270 to provide the stopping action required for a staple 230 to be positioned, positive stops 300 were developed in the upper portion of cartridge 240 about which the lifter fits and slides. With this design there is no reliance on the lifter 270 itself to keep the staple 230 from moving further for-

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ward as it is being forced out of the plane of staple stack 252 and into the path of driver 210. Prevention of staple double feeding and rotation is significantly improved. The lifter 270 is now called on to only drop the staple into place. In addition, the increased track surfaces provide greater constraints on the undesired motions of the lifter 270.

[0049] As can be further seen from Figures 10 and 17, the lifter 270 can only be pushed up by the driver 210 if there is a staple ready for fire located beneath it. With the last staple fired, the lifter 270 falls to a position where the driver 210 contacts a perpendicular rear surface 271 on lifter 270 rather than a more typical angled surface. This surface 271 is the same surface which prevents double feeding of staples 230 from stack 252 into the path of driver 210. As the driver 210 does not have a sloped surface at this contact point, the driver is positively stopped. Since the driver 210 is stopped at a point before that normally associated with a complete staple firing, the fact that a cartridge 240 is empty will be evident to the surgeon.

[0050] The invention has been described in connection with a particularly preferred embodiment. However, it is to be understood that it is only the claims of the invention which are meant to describe this invention.

Claims

1. In combination a stapling mechanism (150) and staples (230) comprising an actuation mechanism, a cartridge (240) containing a stack of staples (230), a firing mechanism for forming said staples (230), said firing mechanism comprising a driver (210) and an anvil (250), and a transfer mechanism engageable with said driver (210) and capable of transferring said staples (230) from said stack to said anvil (250), and said transfer mechanism comprising a lifter (270) positioned in said cartridge (240) to be movable transverse to the longitudinal axis of said cartridge (240) characterised in that said lifter (270) contains a sloped surface sloping in a direction from the driver (210) to the anvil (250), said staples (230) engageable with said sloped surface to move from said staple stack and into the path of said firing mechanism.
2. The stapling mechanism (150) and staples (230) of claim 1 further comprising a planar face on said lifter (270), such that said driver (210) is engageable with the forwardmost staple (230) on said stack engaged with said planar face on said lifter (270), such that said driver (210) is capable of stripping said staple (230) from said lifter (270), moving said staple (230) along said sloped surface, and positioning said staple (230) on said anvil (250) for forming.
3. The stapling mechanism (150) and staples (230) of

claim 2 further including a stop means (271) on said lifter (270), said stop means (271) engageable with said driver (210) when there are no longer any staples loaded in said cartridge (240).

4. The stapling mechanism (150) and staples (230) of claim 2, wherein said staple stack is contained in a track formed within said cartridge (240) and said staples (230) are constrained in said stack by the planar face on said lifter (270).
5. The stapling mechanism (150) and staples (230) of claim 1, wherein said cartridge (240) is arranged such that said staples (230) lie along a longitudinal axis of said cartridge (240) in a stack, and each of said staples (230) having a pair of legs (232) connected by a crown (234), said crown (234) having a distal skin-facing side opposite a proximal side, and said crown (234) further containing a pair of notches (236) in its surface, said notches (236) indented into said distal side, and each said staple (230) arranged in said stack such that said notches (236) are contacted on said distal side by a pair of legs (232) of an adjacent staple (230).
6. The stapling mechanism (150) and staples (230) of claim 1, wherein said cartridge (240) is circular and is at least 10mm in diameter.
7. The stapling mechanism (150) and staples (230) of claim 1, wherein there are at least twelve of said staples (230) in said stack.
8. The stapling mechanism (150) and staples (230) of any of the preceding claims, wherein said cartridge (240) is rotatable about said actuation mechanism.

Patentansprüche

1. Kombination eines Klammermechanismus (150) mit Klammern (230) umfassend einen Betätigungsmechanismus, ein Magazin (240) mit einem Stapel von Klammern (230), einen Auslösemechanismus zum Formen der Klammern (230), wobei der Auslösemechanismus einen Stößel (210) und einen Amboß (250) umfaßt sowie einen mit dem Stößel (210) zusammenwirkenden Überführungsmechanismus, welcher die Klammern (230) von dem Stapel zum Amboß zu überführen vermag und der Überführungsmechanismus einen in dem Magazin (240) positionierten, quer zur Längsachse des Magazins (240) beweglichen Heber (270) umfaßt, dadurch gekennzeichnet, daß der Heber (270) eine geneigte Oberfläche aufweist, die in einer Richtung vom Stößel (210) zum Amboß (250) hin abfällt und die Klammern (230) auf der geneigten Oberfläche aufliegen, um von dem Stapel der Klammern in die Bahn des Auslösemechanismus bewegt zu wer-

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den.

2. Klammmechanismus (150) und Klammern (230) nach Anspruch 1 weiterhin umfassend eine ebene Stirnfläche an dem Heber (270), so daß der Stößel (210) an die vorderste Klammer (230) in dem Stapel anlegbar ist, an welcher die ebene Stirnfläche des Hebers (270) anliegt, so daß der Stößel (210) die Klammer (230) vom Heber (270) abzustreifen, sie an der geneigten Fläche entlang zu bewegen und sie auf dem Amboß (250) zur Formung zu positionieren vermag.
3. Klammmechanismus (150) und Klammern (230) nach Anspruch 2, welcher weiterhin auf dem Heber (270) eine Stoppeinrichtung (271) aufweist, wobei die Stoppeinrichtung (271) an den Stößel (210) anlegbar ist, wenn sich keine Klammern mehr in dem Magazin (240) befinden.
4. Klammmechanismus (150) und Klammern (230) nach Anspruch 2, bei welchen sich der Klammerstapel in einer in dem Magazin (240) ausgebildeten Spur befindet und die Klammern (230) dort durch die ebene Stirnfläche des Hebers (270) im Stapel zusammengehalten werden.
5. Klammmechanismus (150) und Klammern (230) nach Anspruch 1, bei welchen das Magazin (240) derart angeordnet ist, daß die Klammern (230) entlang einer Längsachse des Magazins (240) in einem Stapel liegen und jede der Klammern (230) ein Paar Schenkel (232) hat, die durch einen Kopf (234) verbunden sind, wobei der Kopf (234) gegenüber einer proximalen Seite eine distale, der Haut zugewandte Seite hat und der Kopf (234) weiterhin ein Paar Kerben (236) in seiner Oberfläche aufweist, die Kerben (236) auf der distalen Seite eingekerbt sind und jede Klammer (230) derart in dem Stapel angeordnet ist, daß die Kerben (236) auf der distalen Seite von einem Paar Schenkel (232) einer benachbarten Klammer (230) berührt werden.
6. Klammmechanismus (150) und Klammern (230) nach Anspruch 1, bei welchen das Magazin rund ist und einen Durchmesser von mindestens 10 mm hat.
7. Klammmechanismus (150) und Klammern (230) nach Anspruch 1, bei welchen sich mindestens zwölf Klammern (230) im Stapel befinden.
8. Klammmechanismus (150) und Klammern (230) nach einem der bisherigen Ansprüche, bei welchen das Magazin (240) um den Betätigungsmechanismus drehbar ist.

Revendications

1. En combinaison, un mécanisme d'agrafage (150) et des agrafes (230), comportant un mécanisme de manoeuvre, une cartouche (240) contenant une pile d'agrafes (230), un mécanisme de tir pour mettre en forme lesdites agrafes (230), ledit mécanisme de tir comprenant un entraîneur (210) et une enclume (250) et un mécanisme de transfert qui peut venir en prise avec ledit entraîneur (210) et transférer lesdites agrafes (230), depuis ladite pile, jusqu'à ladite enclume (250), et ledit mécanisme de transfert comprenant une came (270) placée dans ladite cartouche (240) pour se déplacer transversalement par rapport à l'axe longitudinal de ladite cartouche (240), caractérisé par le fait que ladite came (270) contient une surface inclinée en pente selon la direction allant de l'entraîneur (210) à l'enclume (250), lesdites agrafes (230) pouvant venir en prise avec ladite surface inclinée pour passer, depuis ladite pile d'agrafes, sur le chemin dudit mécanisme de tir.
2. Mécanisme d'agrafage (150) et agrafes (230) de la revendication 1, comportant en outre, sur ladite came (270), une face plane telle que ledit entraîneur (210) peut venir en prise avec l'agrafe la plus en avant (230) de ladite pile en prise avec ladite face plane de ladite came (270), de façon que ledit entraîneur (210) puisse détacher ladite agrafe (230) de ladite came (270), amener ladite agrafe (230) le long de ladite surface inclinée, et placer ladite agrafe (230) sur ladite enclume (250) pour la mettre en forme.
3. Mécanisme d'agrafage (150) et agrafes (230) de la revendication 2, incluant en outre, sur ladite came (270), un moyen de butée (271), ledit moyen de butée (271) pouvant venir en prise avec ledit entraîneur (210) lorsqu'il n'y a plus d'agrafe chargée dans ladite cartouche (240).
4. Mécanisme d'agrafage (150) et agrafes (230) de la revendication 2, dans lequel ladite pile d'agrafes est contenue dans une piste formée à l'intérieur de ladite cartouche (240) et lesdites agrafes (230) sont maintenues dans ladite pile par la face plane de ladite came (270).
5. Mécanisme d'agrafage (150) et agrafes (230) de la revendication 1, dans lequel ladite cartouche (240) est disposée de façon que lesdites agrafes (230) se situent, le long d'un axe longitudinal de ladite cartouche (240), dans une pile, et chacune desdites agrafes (230) présentant une paire de branches (232) reliées par une traverse (234), ladite traverse (234) présentant une face distale, qui fait face à la peau, opposée à une face proximale, et ladite tra-

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verse (234) contenant en outre à sa surface une
paire d'encoches (236), lesdites encoches (236)
formant une dent dans ladite face distale, et chaque
dite agrafe (230) disposée dans ladite pile de façon
qu'une paire de branches (232) d'une agrafe adja- 5
cente (230) viennent en contact avec lesdites enco-
ches (236) sur ladite face distale.

6. Mécanisme d'agrafage (150) et agrafes (230) de la
revendication 1, dans lequel ladite cartouche (240) 10
est circulaire et a un diamètre d'au moins 10 mm.
7. Mécanisme d'agrafage (150) et agrafes (230) de la
revendication 1, dans lequel il y a au moins douze
desdites agrafes (230) dans ladite pile. 15
8. Mécanisme d'agrafage (150) et agrafes (230) de
l'une quelconque des revendications précédentes,
dans lequel ladite cartouche (240) peut tourner
autour dudit mécanisme de manoeuvre. 20

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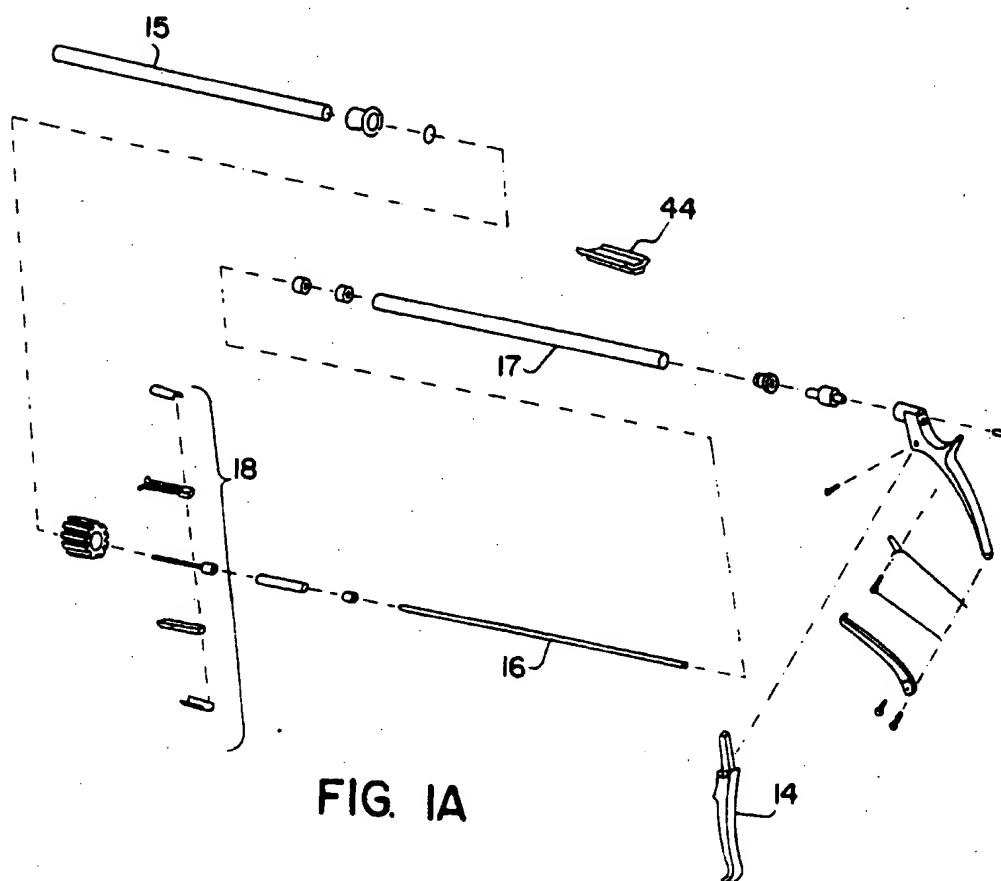
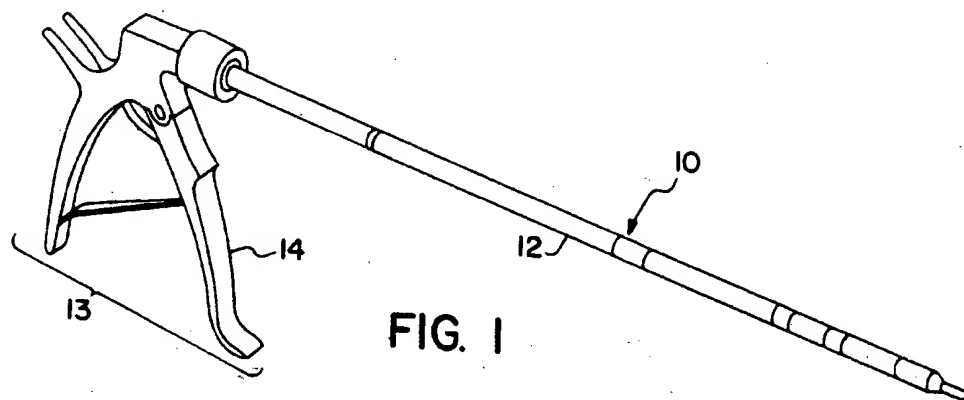
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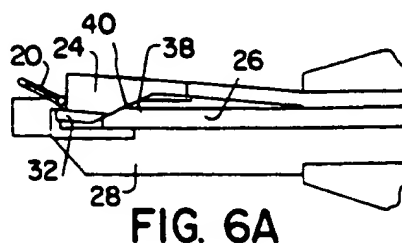
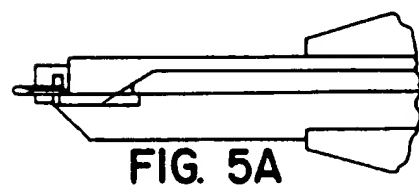
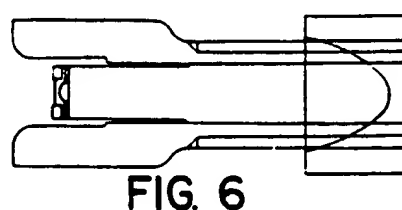
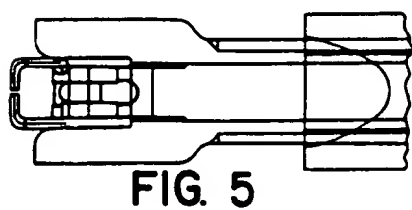
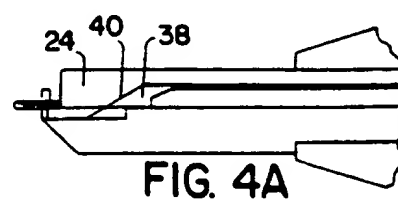
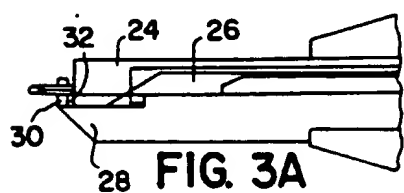
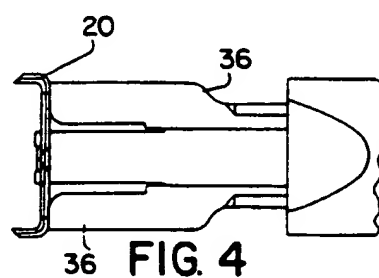
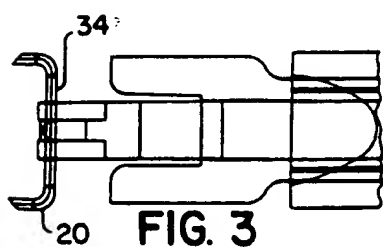
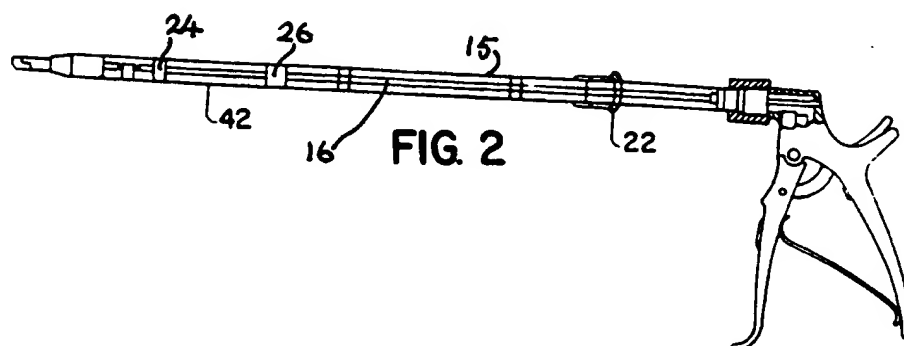
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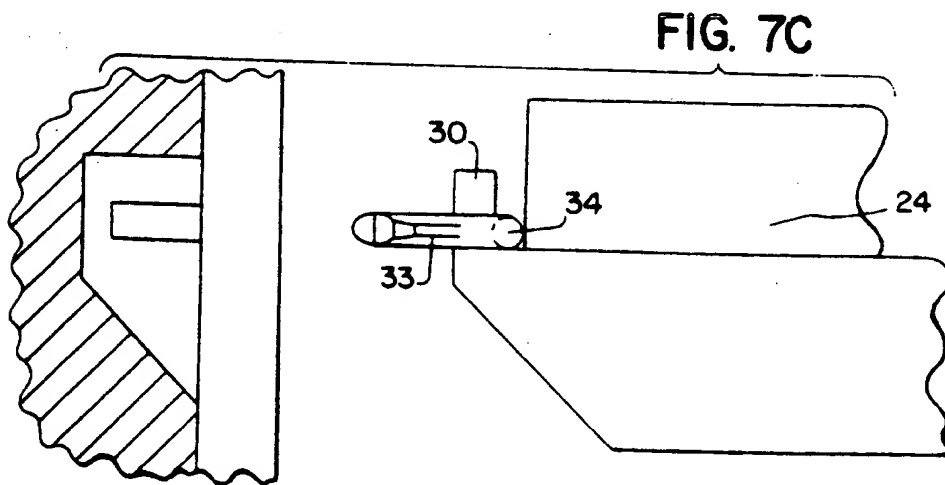
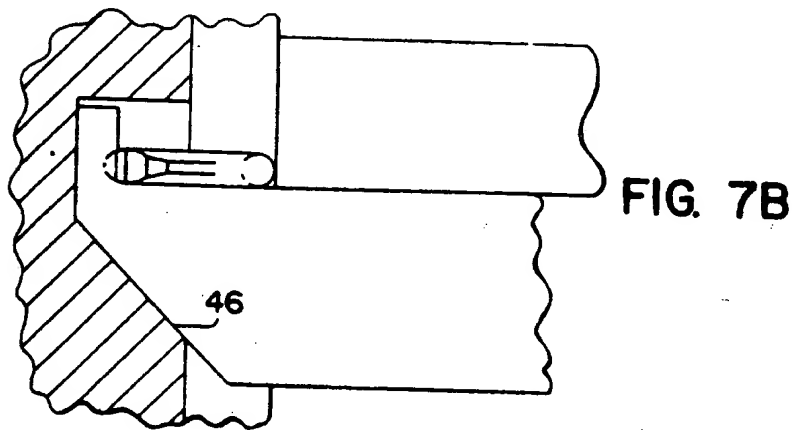
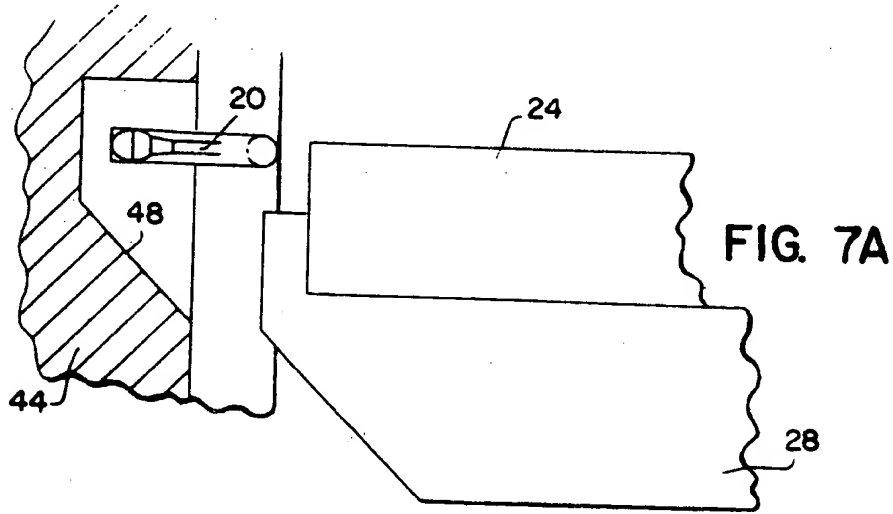
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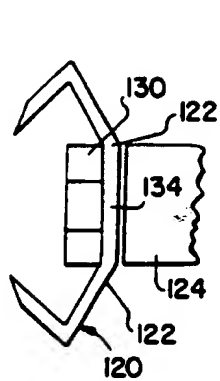


FIG. 8A

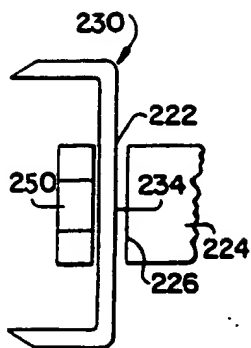


FIG. 8B

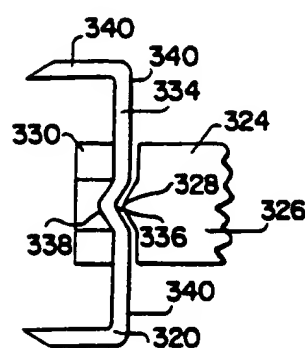


FIG. 8C

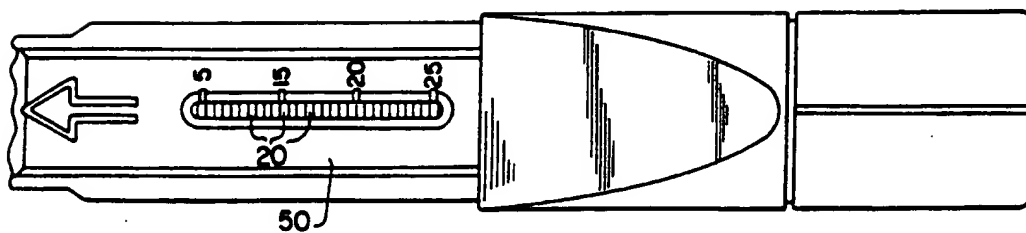
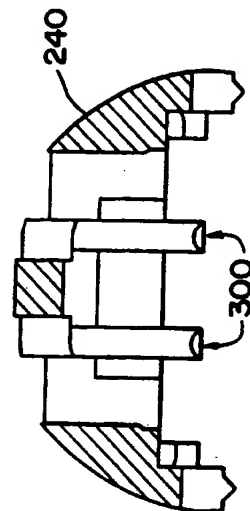
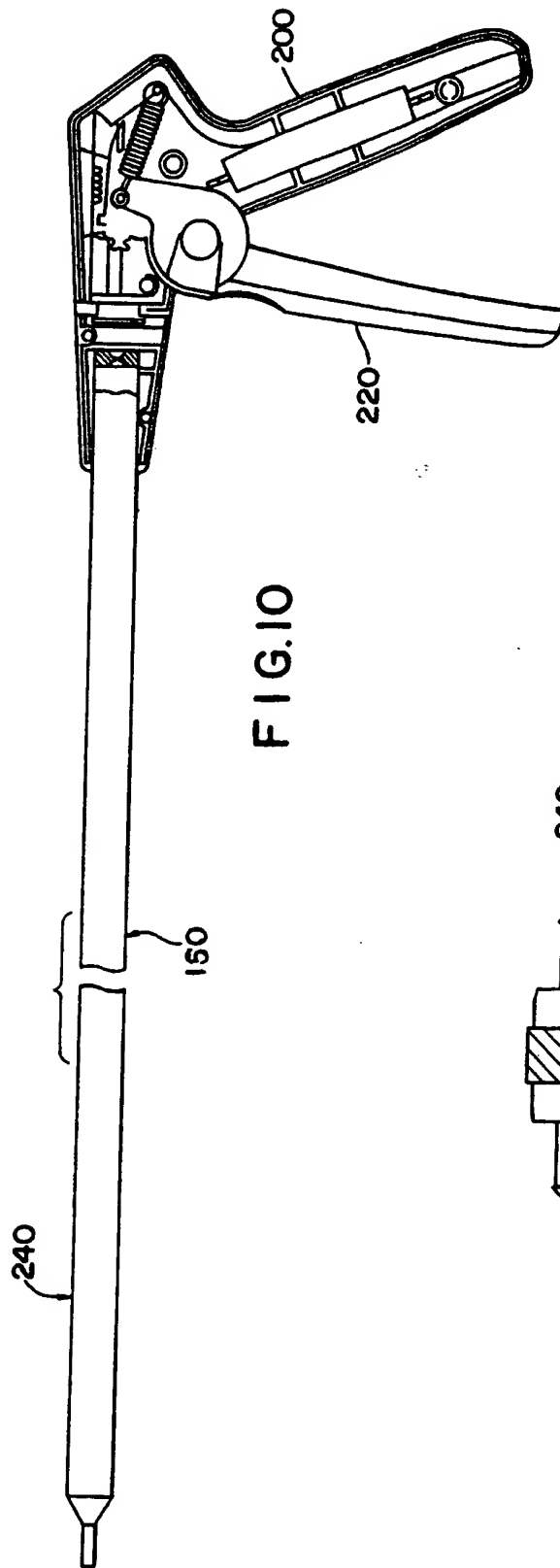


FIG. 9

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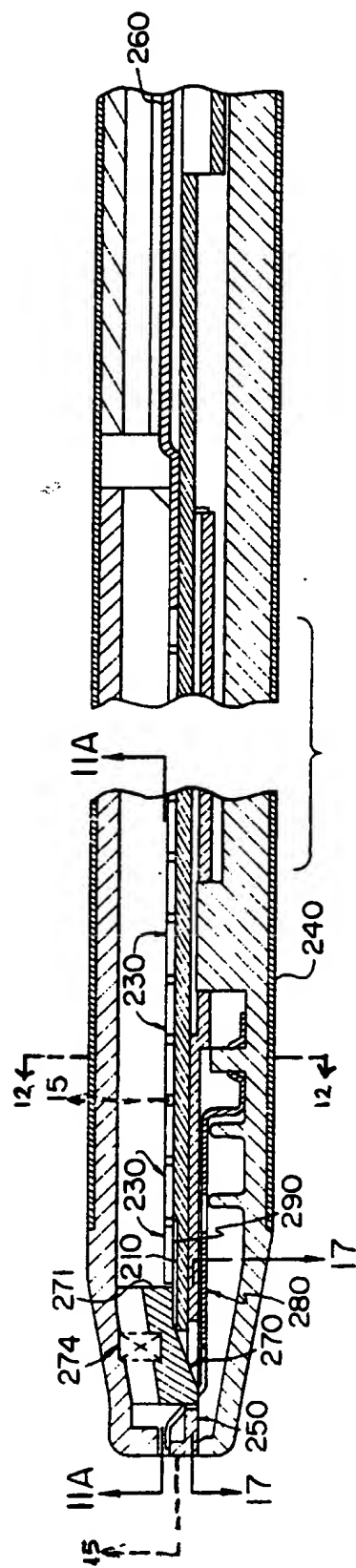
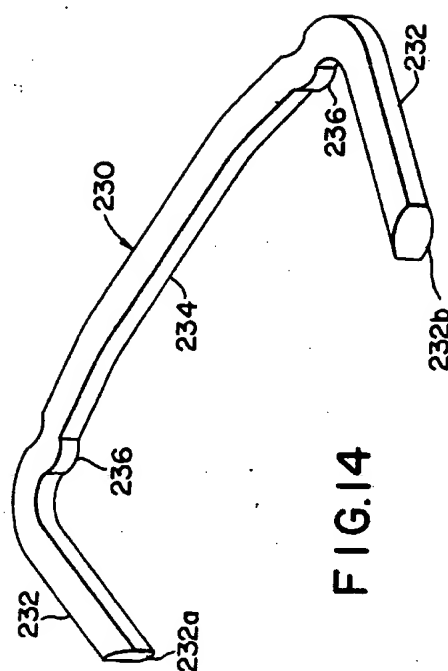
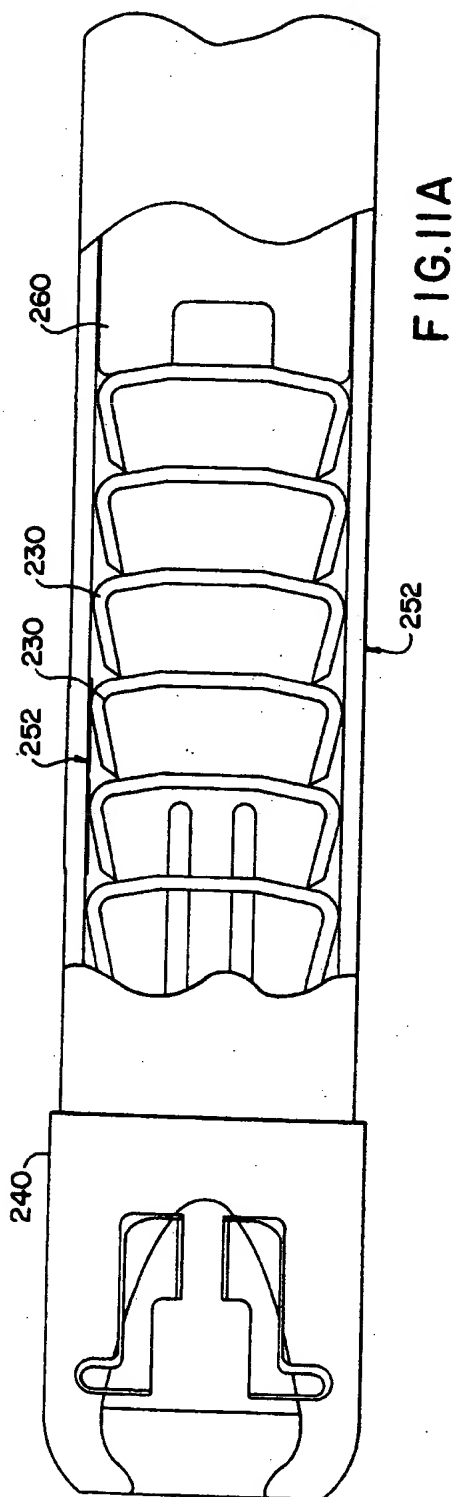


FIG.11

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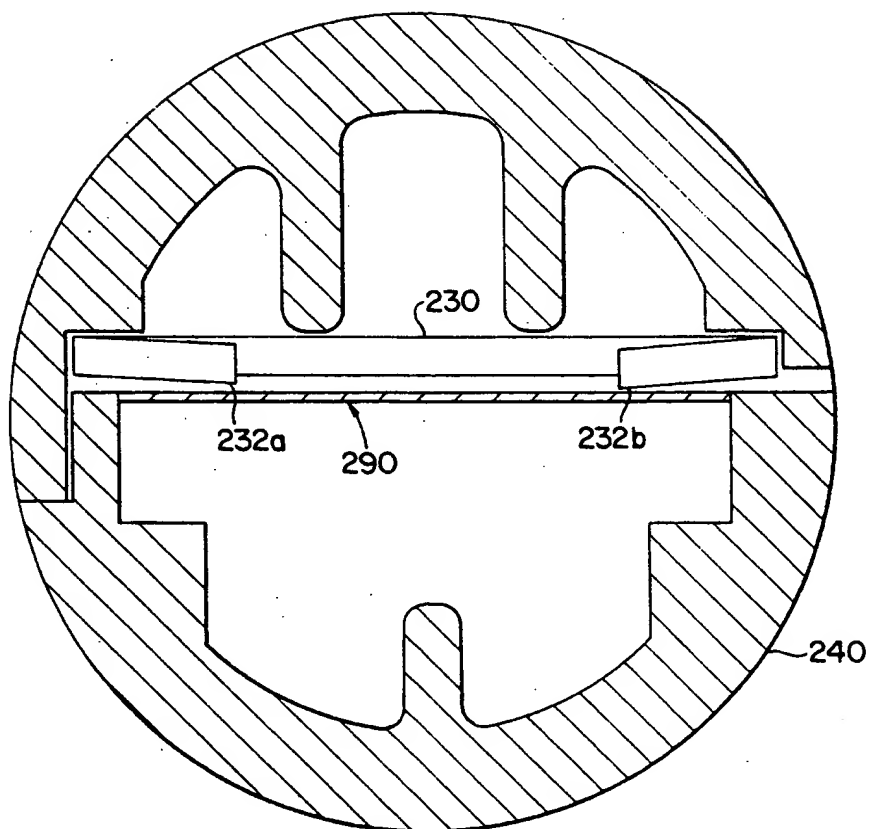


FIG. 12

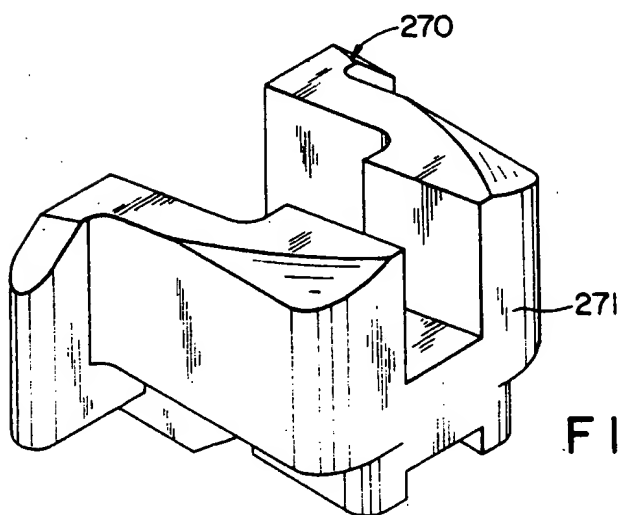


FIG. 16

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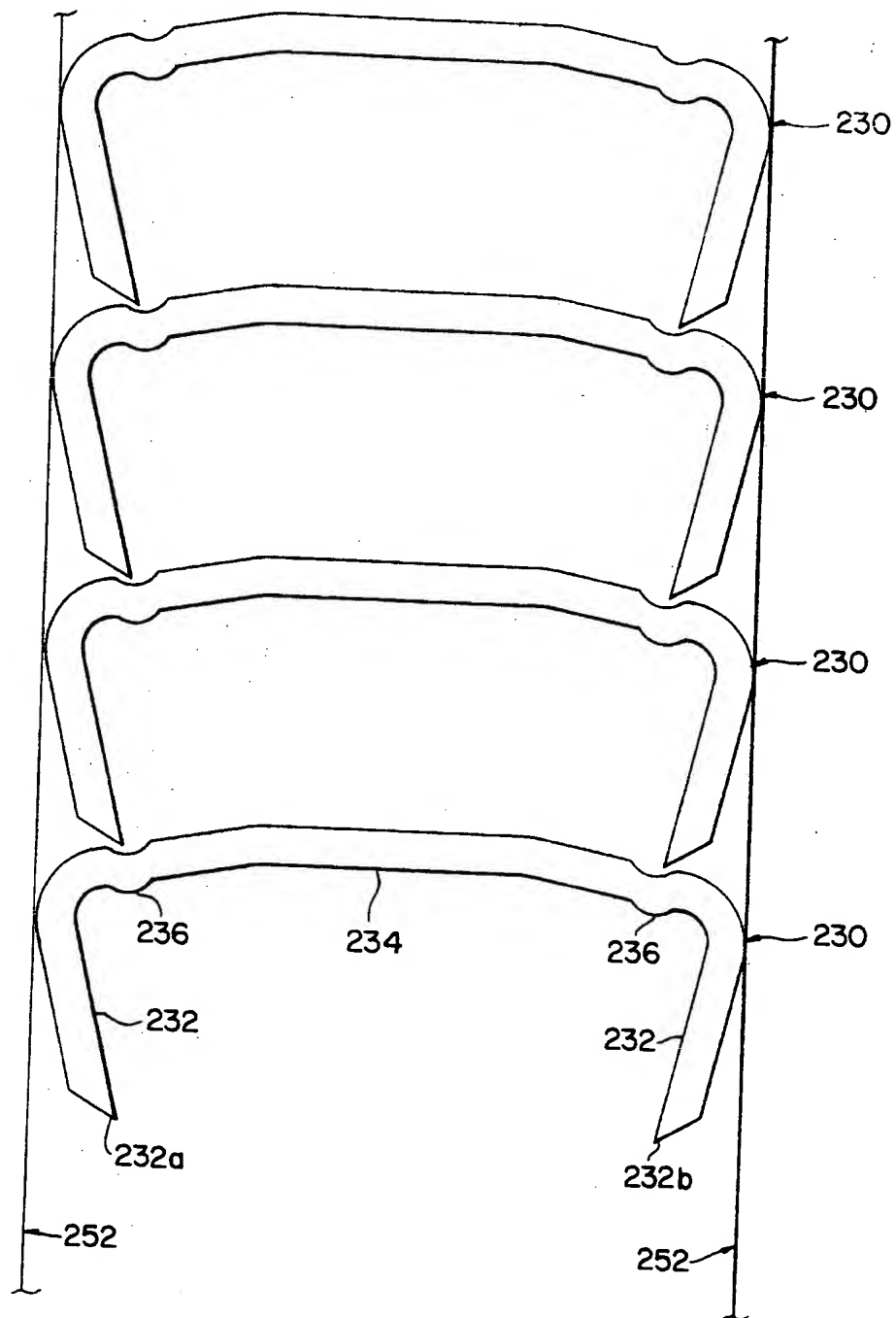


FIG. 13

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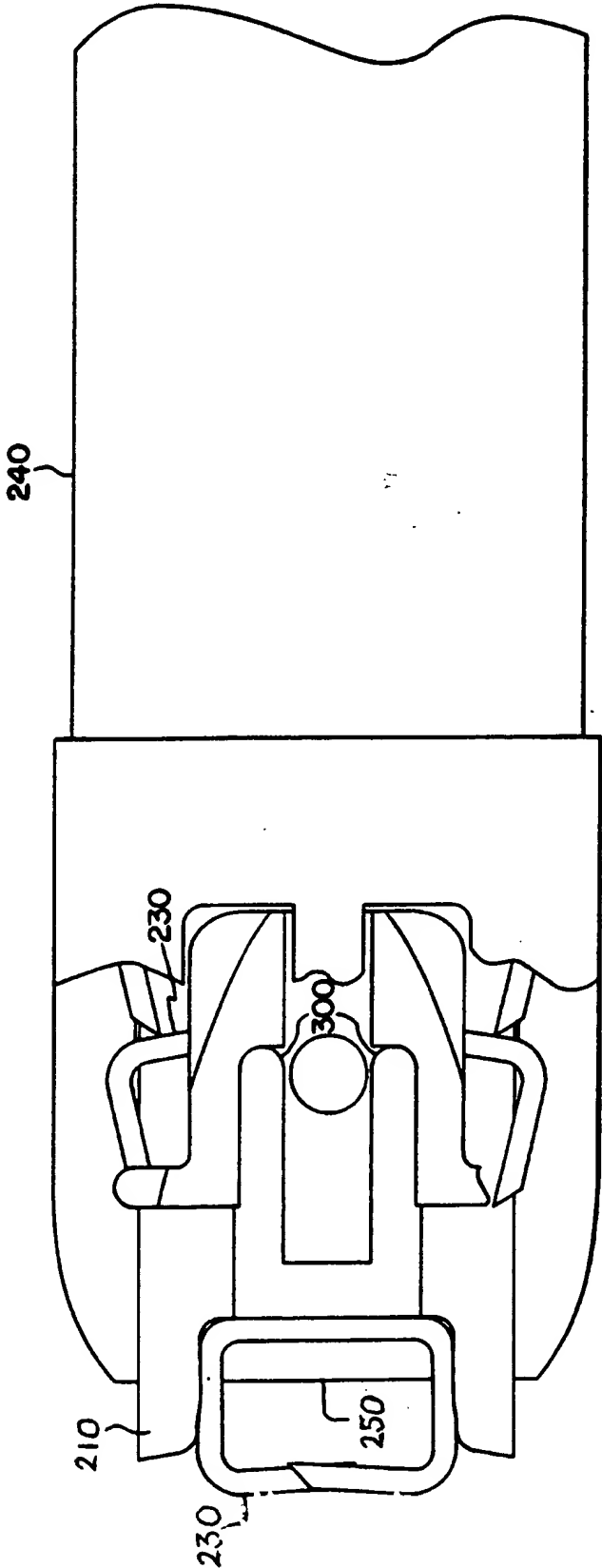


FIG.15

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